

REMARKS

It is respectfully requested that this application be reconsidered in view of the following remarks and that all of the claims remaining be allowed.

Group Election

In the Office Action, the Examiner required the following restriction under 35 U.S.C. § 121:

- I. Claims 1-12, drawn to methods to assess adverse drug reactions by assaying for an allele, classified in class 435, subclass 6.
- II. Claims 13-19, drawn to methods to develop therapies for a cutaneous adverse reaction, classified in class 435, subclass 4.
- III. Claims 20-25, drawn to methods of pharmacogenetic profiling, classified in class 435, subclass 6.

In response, Applicants elect Group I, claims 1-12. The restriction is respectfully traversed for the reasons set forth below.

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (a) The inventions must be independent or distinct as claimed; and
- (b) There must be a serious burden on the Examiner if restriction is not required.

MPEP §803. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. *Id.*

In the present case, Group I and Group III can be searched and examined without serious burden on the Examiner. Group I relates to methods of assessing the risk of a patient for developing an adverse drug reaction in response to a drug, comprising determining the presence of an HLA-B allele selected from the group consisting of HLA-B\* 1502, HLA-B\*5801 and HLA-B\*4601. Group III relates to methods of pharmacogenomics profiling comprising determining the presence of at least one HLA-B allele selected from the group consisting of HLA-B\*1502,

HLA-B\*5801, and HLA-B\*4601. Since both groups include determining the presence of an HLA-B allele selected from the group consisting of HLA-B\*1502, HLA-B\*5801, and HLA-B\*4601, in the course of searching and examining Group I, Group III would essentially be searched and examined. This observation is supported by the fact that the Group I and Group III claims are classified in the same class and subclass.

Thus, Group I and Group III can be searched and examined without serious burden on the Examiner, and Applicants respectfully request rejoining of Group I and Group III. Upon such rejoicing, Applicants would elect the rejoined group, containing claims 1-12 and 20-25.

Further Restriction

If Group I is elected, the Examiner requires the further election of:

- A. one HLA-B allele: HLA-B\*1502, HLA-B\*5801, or HLA-B\*4601;
- B. one drug with respect to claims 2-4: carbamazepine, allopurinol, phenytoin, sulfasalazine, amoxicillin, ibuprofen, or ketoprofen; and
- C. a genetic marker with respect to claim 12: HLA-DRB1\*1202, Cw\*0801, Cw\*0806, A\*1101, MICA\*019, or Cw\*0302.

If Group II is elected, the Examiner also requires the election of:

- A. one HLA-B allele (HLA-B\*1502, HLA-B\*5801, or HLA-B\*4601) or one combination of the alleles; and
- B. one drug with respect to claims 15-18: carbamazepine, allopurinol, phenytoin, sulfasalazine, amoxicillin, ibuprofen, or ketoprofen.

If Group III is elected, the Examiner further requires the election of one HLA-B allele (HLA-B\*1502, HLA-B\*5801, or HLA-B\*4601) or one combination of the alleles.

In response and further to Applicants' election of Group I, Applicants elect HLA-B\*1502, carbamazepine, and Cw\*0801.

The restriction is respectfully traversed. HLA-B\*1502, HLA-B\*5801, and HLA-B\*4601 are alleles of the HLA-B locus, and they share a structural similarity. Pursuant to MPEP §803.04, up

to ten nucleotide sequences can be examined in a single application without restriction. Similarly, it would not be unduly burdensome for the Examiner if three alleles of the same locus are examined together. Consequently, Applicants respectfully request that the restriction with respect to HLA-B\*1502, HLA-B\*5801, and HLA-B\*4601 be withdrawn.

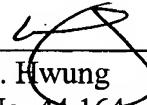
Notwithstanding this traversal, Applicants note that the Examiner set forth linking claims. For example, claims 1 and 5-12 link the HLA-B alleles, drugs and adverse drug reactions<sup>1</sup> in Group I (page 6 of the Office Action). Accordingly, Applicants understand that claims 1 and 5-12 will be examined in their entirety with respect to the HLA-B alleles, drugs and adverse drug reactions<sup>2</sup>, and the corresponding restrictions will be withdrawn if any of these claims is found allowable.

Early examination of this application on the merits is earnestly solicited. In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is requested to call the undersigned at (650) 839-5044.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: April 3, 2006

  
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<sup>1</sup> Although the Office Action states adverse drug reactions in this sentence, Applicants believe that it means genetic markers (recited in claim 12) instead.

<sup>2</sup> Or genetic markers. See footnote 1.